REMARKS/ARGUMENTS

In response to the Examiner's rejection of claim 3 under 35 U.S.C. §112 paragraph 2, it is pointed out that the present claims are method claims for medical treatments which combine certain classes of pharmaceutical agents for unexpected medical utility. In the context of the method invention, one of skill in the art would expect success from using any member of the recited class of materials regardless of the particular member of the class chosen. The Examiner has cited *University of California v. Eli Lilly & Company*, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). The *Lilly* case was not decided on the second paragraph of §112 (which is the Examiner's rejection here) related to claim language ambiguity. Rather, *Lilly* was decided on the first paragraph of §112 (insufficient support in the written specification). *Lilly* held that the molecular biology products claimed required molecular structure in the disclosure. In *Lilly*, all involved claims were product claims. See 43 U.S.P.Q.2d at page 1401 where the claims at issue are summarized. Claim 1 is representative:

> "A recombinant *plasmid* replicable in procaroytic host containing within its nucleotide sequence . . . ."

In *Lilly*, the patentee had attempted to claim DNA sequences but had failed to provide the DNA sequence information. At page 1405, the *Lilly* court notes:

> "[A] description of rat insulin cDNA is not a description of the broad classes of vertebrate or mammalian insulin cDNA. A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 U.S.P.Q.2d at 1606; *In re Smyth*, 480 F.2d 1376, 1383, 178 U.S.P.Q. 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . .").

That is entirely different from method claims, such as the claims at issue here, which patentees frequently set forth as a series of steps to be performed, often without any structural wording at

all. It is the function performed at each step that is relevant. Whether the description properly enables one of skill in the art to perform the method requires only that representative examples be provided (as applicant has done here). Claim 3, which further requires administering androgen taught the function of activating the androgen receptor. Those of skill in the art would, therefore, expect success regardless of what particular androgen might be chosen from among the many that are well-known in the art. In the context of the invention, the various available androgens are substantially interchangeable for purposes of the skilled artisan's expectation of success. In the context of the method claims, it is function and not structure that matters. The *Hirschler* case cited in applicant's prior response is more on point than the *Lilly* case. Analogous to applicant's present claims, *Hirschler* involved method claims and utilization of classes of materials.

Claims 1, 3-6 and 13-28 stand rejected by the Examiner under 35 U.S.C. §103 is allegedly obvious over Labrie '720, Labrie '201, and applicant's alleged admission regarding the prior art at page 2, lines 3-4. However, these three references, neither alone nor in combination, disclose the use of a SERM such as EM-652.HCl for the treatment of menopausal symptoms. The cited language in the specification (page 2, lines 3-4) discusses the use of estrogens for this purpose -- not antiestrogens or SERMS. The Examiner argues at page 5 of the Office Action that "Labrie et al. (WO 96/26201) at page 5, third paragraph, teaches that the compounds therein are useful in the treatment of estrogen-related diseases such as breast cancer, uterine cancer and ovarian cancer during estrogen therapy in menopausal women (emphasis added). However, applicant has been unable to find any such discussion of estrogen therapy in the language cited by the Examiner. The third paragraph of page 5 of the '201 reference is reproduced below:

> "It is another object of the invention to provide therapeutic compounds and compositions useful in the treatment of estrogen-related diseases (e.g., diseases whose onset or progress is aided by activation of the estrogen receptor). These diseases include, but are not limited to breast cancer, uterine cancer, ovarian cancer, endometriosis, uterine fibroma, precocious puberty and benign prostatic hyperplasia."

The above language does not discuss treating menopause, or suggest using the disclosed antiestrogens for such treatment. Indeed, the '201 prior art is clearly directed to estrogen-

exacerbated diseases such as breast cancer which are well-known to respond adversely to estrogens. It is the purpose of the '201 prior art to provide estrogen receptor antagonists which will prevent estrogen receptor activation. As the '201 prior art seeks to avoid estrogenic activity, this prior art unequivocally teaches away from utilizing the compounds disclosed therein for estrogen receptor activation or for treatment of conditions such as menopause which respond favorably to estrogens. Instead, the '201 prior art is unequivocally directed to the treatment of diseases which respond adversely to estrogens. One of skill in the art would not be expected to utilize the '201 compounds (which '201 discloses to be useful against diseases which respond negatively to estrogens) in a corresponding treatment of disorders which respond positively.

The final patent that the Examiner cited in the first §103 rejection is U.S. Patent 5,362,720. Specifically, the Examiner argues that columns 1 and 2 of the '720 reference disclose the use of antiestrogens for menopausal therapy. However, columns 1 and 2 relate instead to various cancers and the treatment of those cancers. The only mention of menopausal therapy is at column 1, lines 30-40 where use of estrogens and progestins in combination is briefly discussed. However, progestins are not antiestrogens or SERMs. Thus, the '720 prior art suffers from the same defects as the other cited prior art. There is no indication that antiestrogens or SERMs should be utilized. There is no *prima facie* case of obviousness. As noted at M.P.E.P. § 706.02(j):

> "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991)." (Emphasis added)

A *prima facie* case of obviousness requires that every element of the claim be present in the art that the Examiner seeks to combine. Not only is it not proper to combine the art cited here (given that much of the prior art is directed to treating estrogen exacerbated diseases instead of estrogen aided conditions like menopause), but even if the combination were made, there remains no teaching in any of the three cited references that antiestrogens or SERMs should be utilized for menopause. In other words, an entire limitation of the claims remains missing even if all of the references are combined.

In the Examiner's second obviousness rejection, the same references discussed above are utilized in connection with a further reference, U.S. Patent 5,780,460. The added reference relates only to the use of DHEA. This reference, too, fails to disclose or suggest the use of antiestrogen or SERM for the treatment of menopausal symptoms.

Accordingly, it is urged that the rejections under 35 U.S.C. §103 should be withdrawn.

It is believed that the application is now in condition for allowance.

EXPRESS MAIL CERTIFICATE

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail to Addressee (mail label #EV342603597US) in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, Alexandria, VA 22313-1450, on June 17, 2004:

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